

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

Track One Cases

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE
MARKETING CAUSATION OPINIONS OF MARK SCHUMACHER,
ANNA LEMBKE, AND KATHERINE KEYES**

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I. INTRODUCTION

This is a targeted motion that seeks to exclude causation opinions regarding the purported effects of Defendants' marketing by three non-economists who have no background or experience in marketing. Drs. Mark Schumacher (an anesthesiologist), Anna Lembke (a psychiatrist), and Katherine Keyes (an epidemiologist) have no training or experience in marketing, much less in pharmaceutical marketing. And they have no economic training in causation analyses pertaining to pharmaceutical marketing—and have not even attempted to run any such analyses here. Nonetheless, Plaintiffs intend to proffer Schumacher, Lembke, and Keyes to opine that, among other things, Defendants' marketing misled physicians and was *the cause* of what Plaintiffs concede is a highly complex and multi-faceted health problem—the rise in opioid-related morbidity and mortality in the Track-One Counties.¹

The marketing causation opinions of all three should be excluded under controlling law for three fundamental reasons. *First*, Schumacher, Lembke, and Keyes are not qualified to give such opinions. None has a degree, training, or experience in pharmaceutical marketing or any other subject that would render them capable of determining whether Defendants' marketing, as opposed to numerous other factors, persuaded unidentified numbers of physicians in Summit and Cuyahoga Counties to write improper opioid prescriptions—much less whether such marketing was the cause of all opioid abuse and misuse in those counties. None has experience in the complex regulatory framework that governs pharmaceutical marketing. And neither Schumacher nor Lembke have any training in economic analyses capable of controlling for any of the numerous different factors that impact opioid prescribing, diversion, addiction, and mortality—and, to the extent Keyes has economic training, she has made no effort to conduct such an analysis here.

¹ See, e.g., Keyes Report, attached as Exhibit 1, at 22; Lembke Report, attached as Exhibit 3, at 4-6, 14-21, 32-33, 37, 58, 63, 66, 68-70, 73, 75-79, 97; Schumacher Report, attached as Exhibit 5, ¶¶ 9, 58, 60, 82, 84.

Second, Schumacher, Lembke, and Keyes' marketing causation opinions are unreliable because they employed no methodology (much less a reliable one) to reach those opinions. Most notably:

- They did not conduct any statistical analyses to understand what role, if any, marketing by the Defendants played in the rise of opioid misuse or abuse in Ohio (or the Counties).
- They spoke to no physicians or patients in the Counties and did not conduct any survey regarding pharmaceutical marketing. To that end, they could not identify a single prescriber misled by a single statement in either of the Counties.
- They made no effort to account for the many different factors—apart from any alleged marketing—that impact prescribing and opioid abuse and mortality in the Counties.
- They did not examine each Defendant's marketing (if any) independently and made a single causation opinion as to Defendants generally.

At most, Schumacher, Lembke, and Keyes attempt to utilize a few general studies about marketing to contend that Defendants are responsible for the opioid abuse crisis in the Counties, without any *actual* analysis of what actually happened there. Their marketing causation opinions are therefore unreliable and will not assist the jury.

Lastly, allowing Schumacher, Lembke, and Keyes to provide testimony regarding the causal effect of Defendants' marketing—when they are not qualified to do so and did no analysis of the impact of any specific marketing in the Counties—would grossly prejudice the Defendants at trial. Causation is a critical issue. Schumacher, Lembke, and Keyes should not be able to offer unsupported and aggregate conclusions at trial on this critical issue. Under Rule 403, the prejudice of their causation opinions would grossly outweigh any probative value (to which there is none).

In short, Schumacher, Lembke, and Keyes are not qualified to give any affirmative causation opinion regarding the supposed effects of any Defendants' marketing on the Counties. Due to their lack of qualifications and of any sufficiently reliable methodology, their causation

testimony should be excluded under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and the Federal Rules of Evidence 402, 403, and 702.

II. LEGAL ARGUMENT

An expert's opinion must "rest on a reliable foundation." *Daubert*, 509 U.S. at 662. Under these rules, the Court has "a special obligation" to prevent improper testimony from an expert witness. *Kumho Tire Co., Ltd v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert*, 509 U.S. at 589). The marketing causation testimony of Schumacher, Keyes, and Lembke are improper and should be excluded for three independent reasons: (1) they are not qualified to give such opinions; (2) their opinions are unreliable and will not assist the trier of fact; and (3) any probative value is substantially outweighed by the prejudice of such unsupported testimony.

A. Schumacher, Lembke, And Keyes Are Not Qualified To Give Causation Opinions On Defendants' Marketing.

As a threshold matter, Schumacher, Lembke, and Keyes are not qualified to give an opinion on the purported effects of the Defendants' marketing, including whether these activities caused the opioid abuse crisis. To opine as to marketing and its effects, an expert must have specialized expertise and experience in that field. *See, e.g., Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 13022172, at *11 (S.D. Ohio Oct. 2, 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) (striking expert's testimony regarding pharmaceutical manufacturer's marketing because he "lacks marketing and regulatory expertise and therefore would not be an appropriate expert to opine" on manufacturer's promotion); *see also Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006) (finding physician was not qualified to opine on the *specific* effects of particular marketing efforts because he lacked "specialized expertise regarding sales or market analysis" and "had conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field.").

Here, none of these three experts has any specialized knowledge as to marketing generally, pharmaceutical marketing in particular, or the regulatory framework that governs pharmaceutical marketing. Dr. Schumacher is an anesthesiology professor with a Ph.D. in physiology and pharmacology. (See Schumacher Curriculum Vitae (“Schumacher CV”), attached as Exhibit 6). Despite opining that the “driving force of this national catastrophe has been the introduction *and marketing* of long-acting formulations of high-potency opioids” (Schumacher Report, ¶ 58 (emphasis added)), Schumacher *concedes* that he is *not* an expert on marketing. (Schumacher April 23, 2019 Deposition Transcript (“Schumacher Tr.”), attached as Exhibit 9, at 31:1–5). He has never studied and is not trained in marketing (*id.* 18:10–12; 19:2–4; 28:2–4; 30:23–25), does not teach courses on marketing (*id.* at 30:9–11), has not published any work on marketing (*id.* at 30:12–19), and has no degree in marketing (*id.* 30:23–25). Nor does he view himself as an expert in economics or epidemiology. (*Id.* 19:5–7; 38:9–16; 38:24–39:12; 39:13–25.) Because he is not an expert in pharmaceutical marketing (or its effects), he has never given an expert opinion before on the subject matter that Plaintiffs have now asked him to give. (See Schumacher Tr. 15:24–16:3; 16:16–23 (Q: [Y]ou’ve never given an expert opinion with respect to pharmaceutical marketing before, correct? A: That’s correct.)).²

Similarly, Lembke is a psychiatry professor with a medical degree. (See Lembke Curriculum Vitae (“Lembke CV”), attached as Exhibit 4.) As her CV makes clear, she has no specialized training or experience in marketing—much less pharmaceutical marketing. (See Lembke CV.) She has no experience with the regulations governing pharmaceutical marketing. (See Lembke April 24, 2019 Deposition Transcript (“Lembke Tr.”), attached as Exhibit 8, at 27:2–

² To make matters worse, Schumacher also purports to opine on the intent behind the Defendants’ marketing. See Schumacher Report, Ex. 3, ¶ 58. But “[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); see also *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337–38 (S.D. Fla. 2010) (same).

5). She also has never worked or consulted for a pharmaceutical company. (Lembke Tr. 49:25–50:2.) Nor does she have any training in epidemiology. (*Id.* 18:22–24.) And Lembke is not an economist and has no training in statistical causation analyses. (*See* Lembke CV.)

Finally, Keyes is an epidemiology professor with an M.P.H. and a Ph.D. in epidemiology. (*See* Keyes Curriculum Vitae (“Keyes CV”), attached as Exhibit 2.) While she has experience with statistical analyses, her CV alone makes clear that she does not teach marketing and is not an expert on prescription opioids, their indications, or how pharmaceutical companies market their opioid products. (*Id.*) She has had no training or experience in marketing and has conducted no independent research on pharmaceutical marketing. (*Id.*) She has also never worked in marketing for a pharmaceutical company or with any other company. (*Id.*) In fact, she did not even review any marketing materials produced by the Defendants in this case. (Keyes April 29, 2019 Transcript (“Keyes Tr.”), attached as Exhibit 7, at 457:8–10). And Keyes was not even aware of differences between brand and generic manufacturers, including that generic manufacturers of opioids do not promote the safety or efficacy of opioid medicines. (*See id.* at 485:18–486:8.)

Because of their total lack of experience with pharmaceutical marketing and, for Schumacher and Lembke, statistical causation analyses, they are not qualified to give the marketing causation opinions they purport to give. *In re Trasyolol*, 709 F. Supp. 2d at 1337-38. The Court, therefore, should exclude it. *See, e.g., Popovich v. Sony Music Entm’t, Inc.*, No. 1:02 CV 359, 2005 WL 5990223, at *3 (N.D. Ohio May 9, 2005) (holding expert not qualified to give opinion on “marketing or advertising” due to lack of training); *see also Chem. Solvents, Inc. v. Advantage Eng’g, Inc.*, No. 1:10-CV-01902, 2011 WL 1326034, at *7 (N.D. Ohio Apr. 6, 2011) (same); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 884 (E.D. Ark. 2008), *aff’d*, 586

F.3d 547, 571 (8th Cir. 2009) (finding expert’s testimony regarding defendant’s marketing practices should be excluded because it was outside her scope of expertise).

B. The Opinions of Schumacher, Lembke, and Keyes About The Causal Effect Of Defendants’ Marketing Are Unreliable And Inadmissible.

The marketing causation opinions of Schumacher, Lembke, and Keyes should be excluded for another, independently sufficient reason: they are unreliable. An “expert’s conclusions regarding causation must have a basis in established fact and cannot be premised on mere suppositions.” *Rheinfrank*, 2015 WL 13022172, at *3 (quotation marks and citation omitted). Among other things, FRE 702 requires expert opinions to be “the product of reliable principles and methods.” FRE 702(c). Here, Schumacher, Lembke and Keyes’ marketing causation opinions are not the product of any methodology—much less a reliable one. They performed no statistical analyses to determine the effects of Defendant’s marketing, spoke to no patients or physicians in Cuyahoga or Summit County, and considered no other factors besides marketing that may have contributed to opioid-related harms. Taken together, these failings render Schumacher, Lembke and Keyes’ marketing causation opinions inherently unreliable. They should be excluded.

1. Schumacher, Lembke, And Keyes Conducted No Statistical Analysis Of The Effects of Defendants’ Marketing.

The causation opinions of Schumacher, Lembke, and Keyes are not reliable because they did not conduct any statistical analysis whatsoever to determine the effects, if any, on physicians *as a result of any Defendant’s marketing*. For example, Keyes testified that “the opinions that [she] derived at for this report are not specific to any particular manufacturer . . . [and] all of the opinions that [she] arrived at are about the overall emergence of an opioid epidemic in the United States,” not what occurred specifically in Summit and Cuyahoga Counties. (Keyes Tr. 458:16–459:3.) She also testified that she did not even review the Defendants’ marketing materials: “*There was no marketing material that I relied on to form the opinion that is in this report.*” (See Keyes

Tr. 457:14–15 (emphasis added).) Instead, her conclusion that Defendants’ “marketing practices led to consequences for opioid-related harm” (Keyes Rep. at 22), is based on journal articles discussing marketing materials by *other* manufacturers for *other* medications in *other* parts of the country. (See Keyes Tr. 454:17–455:18.) And even those few articles that discussed opioid medications disclose that “it is unclear whether the marketing of opioids influences prescribing”—a point that Keyes was unable to dispute during her deposition. (*Id.* at 472:14–476:23).

While Schumacher reviewed a handful of selected marketing materials produced in this case from some (but not all) Manufacturer Defendants, he testified that he had not conducted any statistical analysis to support his opinion. (Schumacher Tr. 42:24–43:8.) He did no regression analyses to evaluate any opioid marketing by any Defendant. (*Id.* at 42:13–21.) He is giving no opinions on any regression analyses performed by anyone else regarding pharmaceutical marketing. (*Id.* at 42:22–43:8.) Rather, he simply reviewed some marketing materials and then *presumed* that doctors were misled by them. (*Id.* at 342:5–343:22.) In addition, Schumacher conceded that he has no data to determine which prescribers in Cuyahoga or Summit County purportedly relied upon any alleged false marketing by the Defendants in this case. (*Id.* at 370:2–24, 373:5–12, 344:6–345:16.) Absent such data, and evidence showing that any such reliance caused some harm, he cannot provide the causation opinion he tries to give.

In fact, when confronted with one of his own internet postings, Schumacher conceded that marketing may merely be a “*potential* factor” of the opioid abuse crisis generally. (*Id.* at 164:3–20.) Schumacher has done no independent analysis to determine whether marketing—much less

the particular alleged false marketing by the Defendants here—is an *actual* factor. Nor has he reviewed any studies by anyone else regarding that marketing.³

Like Schumacher and Keyes, Lembke testified that she did not “calculate or formulate any of [her] own regression models or statistical analyses in this case[.]” (Lembke Tr. 19:22–25.) Lembke also did not review or conduct any studies on Defendants’ marketing of their opioid medicines; instead, she relied on marketing studies that did not focus on Defendants or the opioid medications at issue in this case and from those studies seeks to speculate that the results would apply to Summit and Cuyahoga prescribers in these circumstances. (*See Id.* 243:3–16.)

In short, none of the three made any attempt to conduct any statistical analyses to understand the scope of any allegedly false marketing by Defendants in Ohio, whether that marketing impacted any Ohio prescribers, and, if so, whether those prescriptions caused any harm to patients in Summit or Cuyahoga Counties. As a result, the entire basis for their marketing causation opinions is unreliable and speculative, and should be excluded. *See In re Prempro Prods. Liab. Litig.*, No. 4:03CV01507-BRW, 2012 WL 12906583, at *3 (E.D. Ark. Aug. 29, 2012) (granting motion to exclude expert’s testimony regarding defendants marketing materials’ effect on physicians after finding it would do no more than “provide a speculative editorial about the alleged nefarious global effects of the[] marketing practices.”).

2. Schumacher, Lembke, and Keyes Did Not Speak To Any Physicians Or Patients In Summit Or Cuyahoga County.

As yet another reason why their causation methodology is flawed, none of the three experts made any attempt to survey any physicians or patients in either Summit or Cuyahoga County. They did not interview any physicians in Summit or Cuyahoga to understand what marketing

³ In fact, Schumacher was not even aware of a marketing study conducted by an Ohio state agency showing that Ohio prescribers are *not* influenced by opioid marketing. (*Id.* at 176:2–181:9.)

materials, if any, they received from what Defendants—not to mention what, if any, marketing materials they relied upon in writing any opioid prescription. They did not survey any Summit or Cuyahoga patients to understand their experiences with opioid medicines. In fact, they conducted *no studies on these key issues* whatsoever. (See Schumacher Tr. 30:18–31:6; 176:13–25; 93:11–96:9; Lembke Tr. 77:20–78:1; 177:10–178:11; Keyes Tr. 49:14–23.)

Without such information, each of these experts can only speculate about causation. They know nothing about what any Summit or Cuyahoga physician may have believed, why he or she may have written an opioid prescription, or why any patient may have become addicted to opioids. They cannot identify any prescribers who were allegedly misled in some way, because they simply do not have the “data” and have not done any analysis. (See Schumacher Tr. 368:14–19.) As such, they should be precluded from giving any marketing causation opinion. See, e.g., *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 556 (excluding testimony because the experts “are not qualified to opine as to what doctors in general think.”); *Allen v. Takeda Pharms. N. Am.* (*In re: Actos (Pioglitazone) Prods. Liab. Litig.*), No. 6:11-md-2299, 2014 U.S. Dist. LEXIS 5289, at *61 (W.D. La. Jan. 14, 2014) (excluding expert’s causation opinion on manufacturer defendants’ marketing because the expert “cannot know what a physician or consumer *actually might have known or done* . . . [the expert] cannot be said to know whether Takeda’s actions *actually caused* consumers ‘to believe’ [and that] what a doctor or consumer *might actually* have believed or *actually done* is, without question, outside of her purview”) (emphasis in original).

3. **Schumacher, Lembke, and Keyes, Did Not Consider The Role Of, Much Less Rule Out, Other Factors Influencing Opioid Prescribing.**

Schumacher, Lembke, and Keyes’ causation opinions regarding the effects of Defendants’ marketing are also unreliable because they all fail to evaluate the impact of other factors (which have nothing to do with Defendants) on opioid-related morbidity and mortality—either in Summit

and Cuyahoga or nationally. *See In re Aredia & Zometa Prods. Liab. Litig.*, 483 F. App'x 182, 190 (6th Cir. 2012) (excluding testimony where expert “admitted that he did no research into alternative risk factors” and he conceded that “he did not rule out” other “exacerbating factors”); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 254 (6th Cir. 2001) (excluding causation expert in part because he failed to analyze data to account for other alternative causes and factors).

For example, despite opining that the marketing of long-acting opioids was the “driving force” of the opioid epidemic, Schumacher testified that he did not consider whether Drug Enforcement Administration or Food and Drug Administration policies “caused or contributed to the opioid epidemic in Ohio.” (Schumacher Tr. 164:25–170:3.) Nor did he consider whether “managed care or reimbursement policies by managed care entities caused or contributed to the opioid epidemic in Ohio.” (*Id.*) Likewise, he did not look at the role and effect of “pill mills” or “actions or inactions taken by local government” or even whether (and when) Ohio implemented a Prescription Drug Monitoring Program. (*Id.*) He similarly did not consider whether the “misuse of opioids by patients in Ohio caused or contributed to the opioid epidemic there.” (*Id.* 171:4–16; 172:4–16.) He did not even consider the alleged conduct of many of the Defendants in this case. (*Id.* 184:7–21; 204:8–13.) He thus performed none of the analyses necessary to provide a viable causation opinion.

Lembke also did not consider other factors—apart from marketing—in reaching her causation opinions. For example, she did not evaluate the influence that hospital administrators, health insurance companies, or other third-party payors have on whether a patient is prescribed opioids. (Lembke Tr. 197:2–9.) She did not consider social and economic factors in determining whether a patient develops opioids use disorder. (*Id.* 90:7–17; 119:6–12; 135:19–136:3; 171:9–172:13.) She did not consider key factors in determining why a patient taking opioid prescriptions

may transition to heroin use. (*Id.* 81:15–82:10; 119:6–12.) And, in concluding that the increase in infectious diseases related to heroin abuse was a result of opioid abuse supposedly stemming from Defendants’ marketing, Lembke did not rule out other potential causes for the increase, such as risky sexual conduct or contraction prior to opioid abuse. (*Id.* 64:16–65:16.)

Lastly, despite blaming the Defendants’ alleged marketing for all “opioid-related harm” (Keyes Report 22), Keyes failed to evaluate any other factors—let alone analyze or control for them. For instance, she did not consider whether formulary coverage had any impact on physicians’ prescribing decisions in Ohio. (Keyes Tr. 480:18–481:16.) She did not consider the role that health insurance companies play in dictating whether a patient is prescribed opioids. (*See* Keyes Tr. 480:2–17.) She did not consider physicians’ medical training and whether that impacted their decisions to prescribe opioids. (*See* Keyes Tr. 478:7–479:14.) Instead, she merely looked at one or two studies about marketing (unrelated to opioids) by other pharmaceutical companies outside of Ohio. (Keyes Report 22.) That is not a methodology.

Because Schumacher, Lembke, and Keyes merely *presumed* that marketing created opioid abuse and failed to consider the various other factors in the increase in opioid misuse and abuse, their causation opinions regarding marketing are inherently unreliable. They should be excluded under *In re Aredia*, *Nelson*, and controlling Sixth Circuit law.

4. Schumacher, Lembke, and Keyes Do Not Consider The Causal Impact Of Any Particular Defendants’ Specific Marketing.

Schumacher, Lembke, and Keyes’ causation opinions also should be excluded because they only purport to opine on the marketing of Defendants in the aggregate, and did not measure, or even consider, the impact of *each Defendant’s* alleged marketing misconduct, to the extent a Defendant even engaged in such marketing. It is well-settled that Plaintiffs cannot simply lump all Defendants together; they must show that “the conduct of *each defendant* was a substantial

factor in producing the harm.” *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) (emphasis added).

But Schumacher, Lembke, and Keyes ignore this basic principle. With respect to their causation opinions, they each lump many if not all of the Defendants together, without distinguishing between them or even examining each of the Defendants’ independent marketing materials, if any. Even worse, Schumacher, Lembke, and Keyes never attempted to measure whether the marketing of each Defendant actually affected a prescriber in either Cuyahoga or Summit County (or if it even reached a prescriber in either County in the first place). Thus, their generalized opinions will not assist the tier of fact because they do not determine causation as to *each Defendant*.

C. The Opinions of Schumacher, Lembke, and Keyes About The Causal Effect Of Defendants’ Marketing Would Mislead or Confuse the Jury and Unfairly Prejudice Defendants.

It is well-settled that “[l]ike all evidence, the admissibility of expert testimony is also subject to a . . . balancing of probative value against likely prejudice under Rule 403.” *United States v. Geiger*, 303 F. App’x. 327, 329 (6th Cir. 2008). Here, allowing Schumacher, Lembke, and Keyes—non-economists who ran no tests and simply presumed a causal effect associated with all marketing—to testify on a core issue like causation would mislead or confuse the jury and unfairly prejudice Defendants. Allowing this testimony would enable Plaintiffs to have the jury hear conclusions about causation over and over again—bells that cannot be unrung even after cross-examination demonstrates the witnesses do not have the qualifications to make the conclusions and did nothing to support them. *See Daubert*, 509 U.S. at 595 (recognizing the potential that “[e]xpert evidence can be both powerful and quite misleading,” and the court’s role is to keep such misleading testimony from reaching the jury under Rules 702 and 403).

III. CONCLUSION

For the foregoing reasons, the Court should exclude the marketing causation testimony of Schumacher, Lembke, and Keyes.

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Industries Ltd.*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 28, 2019, Defendants' Motion To Exclude The Marketing Causation Opinions Of Mark Schumacher, Anna Lembke, And Katherine Keyes, along with the Memorandum of Law, proposed Order, exhibits, and summary fact sheet, were served via email on all attorneys of record consistent with the June 24, 2019 Order setting forth Directions Regarding Filing of Briefs Under Seal.

/s/ Steven A. Reed
Steven A. Reed